AD_____

Award Number: W81XWH-08-1-0755

TITLE: Importance of Virtual Reality to a Controlled Stimulus

PRINCIPAL INVESTIGATOR: Robert McLay

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

REPORT DATE: October 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| **1. REPORT DATE** | **2. REPORT TYPE** | **3. DATES COVERED** |
|---|---|---|
| October 2013 | Annual | 25 September 2012 – 24 September 2013 |

**4. TITLE AND SUBTITLE**
Importance of Virtual Reality to a Controlled Stimulus

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-08-1-0755

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
McLay, Robert N

**E-Mail:** hbilliu@genevausa.org

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

The Geneva Foundation

Tacoma, WA 98402

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

This study is a follow up to two projects, funded by the Office of Naval Research, which demonstrated that Virtual Reality (VR) Exposure Therapy was safe for the treatment of combat PTSD Disorder, and that it worked better than treatment as usual. In this study, we are attempting to discover if the Virtual Realty is actually the active component of the treatment. Participants with PTSD are randomized to receive the same treatment that was successful in the previous projects, or the same treatment in which a simple, still computer image replaces the VR. At the initial onset of the project we were delayed by 6 months for administrative reasons. The project has since that time consistently been 6 months behind, but is otherwise going as anticipated. In the last year, we have continued to recruit, assess, and treat individuals with combat related PTSD. We have completed treatment of a little over half the targeted number of subjects, and within the next 10 weeks, if currently enrolled subjects complete treatment, will reach 75% of our target enrollment. Preliminary analysis from current subjects is showing that the use of the VR does not significantly improve outcomes immediately after treatment. However, at 3-month follow up, subjects who had received VR had greater treatment gains than those in the control condition.

**15. SUBJECT TERMS**

Post Traumatic Stress Disorder, Anxiety, Depression, Virtual Reality, Psychotherapy, Exposure Therapy

| **16. SECURITY CLASSIFICATION OF:** | | | **17. LIMITATION OF ABSTRACT** | **18. NUMBER OF PAGES** | **19a. NAME OF RESPONSIBLE PERSON** |
|---|---|---|---|---|---|
| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | | | USAMRMC |
| U | U | U | UU | 6 | **19b. TELEPHONE NUMBER** *(include area code)* |

**Table of Contents**

**Page**

**INTRODUCTION:** This study is intended to determine if the Virtual Reality (VR) simulator used in Virtual Reality Exposure Therapy (VRET) is the active component when using the technique to treat combat-related PTSD. It is a multi-site, randomized, single blind comparison of VRET versus a control condition that uses all the same components of therapy, except that a single, still computer image is used to focus a subject's attention rather than having him/her use a full, VR simulator. The VRET is conducted in the same fashion as has been previously used to treat combat PTSD. Subjects receive therapy for up to twice a week therapy for ten weeks. Subjects are assessed by independent, blinded raters before and after treatment, and three months later to determine long-term follow up. Success is determined by showing improvements on the Clinician Administered PTSD Scale (CAPS). The study was designed to complete treatment of 80 subjects (40 active and 40 controls) over the course of 4 years. A fifty percent dropout rate was anticipated. The study was to be completed at two military facilities, Naval Medical Center San Diego, and Marine Corps Base Camp Pendleton. Each of those sites contains several, smaller clinics. The first stage of the project was to recruit and train research therapists, and research assistants, to obtain IRB approval to conduct the study, and to set up measures to ensure and monitor protocol adherence and progress. This includes both weekly research meetings, and annual safety and efficacy review in which data is compiled each year to ensure that subjects in either the active or the control condition are not receiving care that is anything less than ideal. Because of funding cuts to the original budget, the study is dependent on including volunteer research therapists and research assistants who work on the project without cost to the grant.

**BODY:**

The project is now entering its final year. Originally, we had anticipated the study ending in September of 2013. However, we received a no-cost extension to stretch out the timeframe on the project to September of 2014 in order to complete targets for recruitment and treatment.

The goal of the project was to treat 80 participants (40 active and 40 controls). To date, we have completed treatment in 70 participants, with 6 more still active in treatment. The ratio of recruitment to completion has gone largely as anticipated. The 76 participants who have currently completed or who are in treatment were drawn from 142 individuals who consented to participate. Of the 142 who were consented, 34 did not qualify based on inclusion and exclusion criteria, 25 elected not to enter treatment (dropped out prior to randomization), 7 dropped out of treatment, 13 completed treatment and post-treatment assessment but were lost to follow up, 5 have completed treatment and are still pending final follow up, and 52 completed treatment and have contributed all follow-up data.

No serious adverse events have been encountered during the study. We run an annual safety review of our data each April. Details of this are shown in the "reportable outcomes section". No safety issues were identified from this review.

Logistically, the project continued along largely as anticipated, but with some delays. We had turnover of several of our volunteer therapists and research assistants. Our primary research assistant (hired by the grant) left the project, and we elected not to replace her as we have volunteers who are capable of continuing that portion of the job, and the credentialing process (which now takes about 6 months) would have meant that any new hire would have a very limited time remaining on the project. Our principal research therapist at Camp Pendleton had to leave for a period of medical absence, which caused us to temporarily close that site. However, the therapist has returned and we are now functioning at the site. Sequestration and then the government shutdown caused us to temporarily cut back on enrolling participants during periods when the volunteer therapists/research assistants and the PI were furloughed. One of our volunteer therapists, who had been our only treating provider using one of our 6 VR machines was re-assigned, causing us to no longer be actively using the machine at that clinic. Another of our therapists changed clinics within NMCSD, starting working at a PTSD-specific program

(Navy OASIS), which, while it caused delays, should ensure a solid pipeline for future recruitment. We had several small breakdowns of VR equipment, but were rapidly able to get this repaired and we were able to maintain five working VR machines for treatment.

Only one item from the statement of work is relevant to the current study period:
Task 2: Month 7 to month 42: Recruit and enroll approximately 8 patients per treatment period, with the expectation that 4 of these will enter VRET or CET treatment phases, and be eligible for intention to treat analysis.

We anticipate that in the next several months were will complete enrollment and treatment of our full target n. Remaining time in the project will then be spent completing long-term assessments, and then moving to data analysis and publication.

**KEY RESEARCH ACCOMPLISHMENTS:**

- Key personnel and procedures in place to conduct and test Virtual Reality Exposure Therapy versus the control condition
- Annual safety and efficacy review was conducted in April, which showed that subjects are improving in both treatments. So far, there are no statistically significant differences between how subjects are performing in the active and control groups. Numerically, the active VR group appears to be doing better at the three month follow up, but the differences are not statistically significant.
- All elements in place to continue to treat subjects, gather data, and complete the study in the following year.

**REPORTABLE OUTCOMES:**

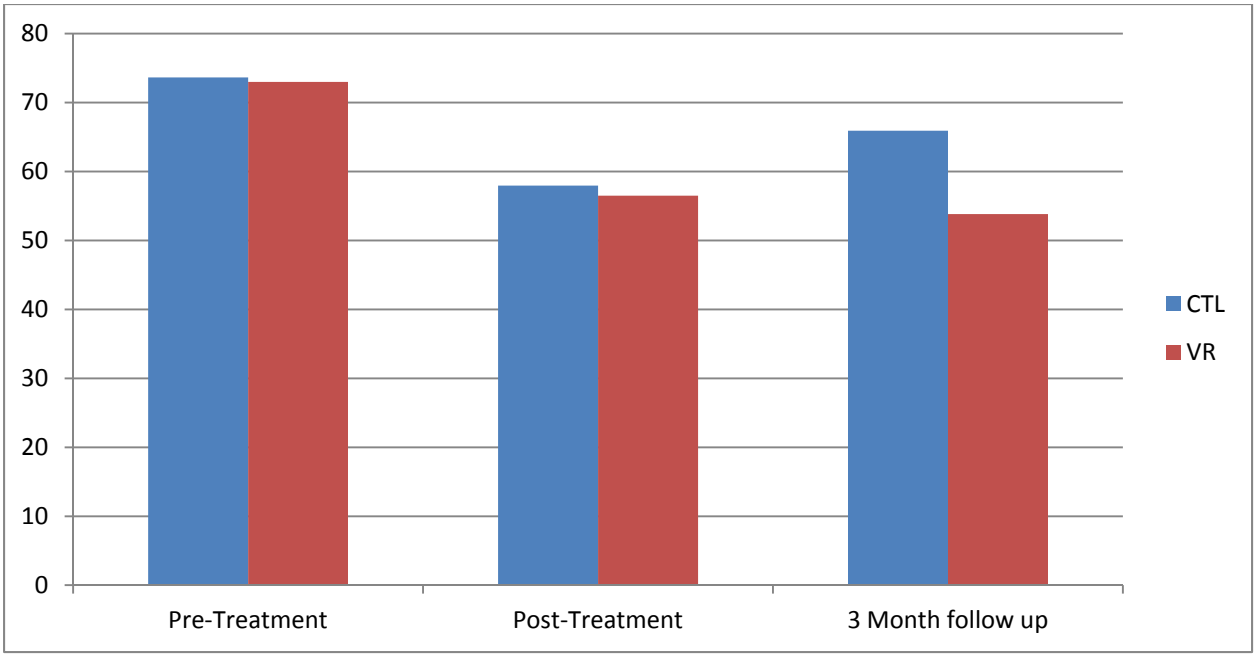
There has been one presentation on the project, "New Options for Military Posttraumatic Stress Disorder" at the American Psychiatric Association annual meeting in San Francisco, CA, May 20 2013. The graph below is taken from that presentation. There were no statistically significant differences between groups at any time point, although it appeared that, numerically, individuals in the VR arm may have been doing better at 3 month follow up after treatment. Graph of this is given in the supporting data section.

**CONCLUSION:** Preliminary findings confirm previous reports that VRET is a safe and effective treatment for combat-related PTSD. So far, however, we do not have sufficient evidence to say that the virtual reality simulator actually improves outcomes when compared to the same techniques used without benefit of the advanced technology.

**REFERENCES:** Not applicable.

**APPENDICES:** None

**SUPPORTING DATA:**




**N= 47, 24 controls & 23 VR. No significant differences.**